

MAY 14 2013

**Section Five (5) - 510(k) Summary**

**510(k) SUMMARY**

[As Required by 21 CFR 807.92(c)]

K123985

**Submitter's Name & Address:**

Sensus Healthcare  
851 Broken Sound Parkway NW  
Suite 215  
Boca Raton, FL 33487

**Contact Person:**

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Fax (561) 948-2071  
kal@sensushealthcare.com

**Date Summary Prepared:**

December 18, 2012

**Device Name:**

Trade/Proprietary Name – SRT-100

Common/Usual Name – Superficial X-ray Radiation  
Therapy System

Classification Name – X-ray Radiation Therapy System  
(21 CFR 892.5900)

Predicate Devices – Topex SRT-100 (K063456)\*<sup>Note 1</sup>

Pantak Superficial X-ray Therapy  
System (K971074)

Gulmay D3100/Xstrahl 100  
(K962613)

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**Device Description:**

The Sensus Healthcare SRT-100 is a complete, stand-alone, x-ray radiation therapy system. It consists of two major separate components:

**Control Console:** Specifically designed module housing the switches and indicators used by the operator to set up and execute x-ray exposures. The controls adjust the machine functions and settings only! There is no treatment planning capability. The Control Console is connected, through a cable, to the Base Unit.

**Base Unit:** The base unit consists of a cabinet containing the high voltage generator, power supply components, cooling system, and an arm/positioning mechanism on which the x-ray tube housing assembly is mounted. A series of Applicators are included, which are affixed to the x-ray port on the x-ray tube housing assembly to limit the x-ray beam and provide fixed Source-to-Skin Distance (SSD). The X-ray Tube-Housing Assembly contains a motorized filter mechanism, which moves the appropriate beam filter into the beam path depending on the kV setting selected by the operator.

**Intended Use:**

The SRT-100 is a low energy x-ray system intended for superficial radiotherapy treatment of primary malignant epithelial neoplasms of the skin and keloids. Applications include basal cell carcinoma, squamous cell carcinoma, Metatypic carcinoma, cutaneous appendage carcinoma, Kaposi's Sarcoma, and the treatment of keloids (note: keloids are benign

**ORIGINAL**

fibrous growths that arise from proliferation of dermal tissue typically arising from injuries to skin tissue).

**Technological Characteristics/Principles of Operation:**

The SRT-100 produces and emits filtered, low energy (50, 70, and 100 kV) x-ray, which is electrically generated using a conventional ceramic x-ray tube. Provision is made to limit the x-rays to a specified treatment field, and to control the delivered dose to the patient through selection and monitoring of energy, emission levels and duration of emission. To mitigate effects of ionizing radiation on healthy cells, and to accumulate more damage in the neoplastic cells and fibrous keloid cells associated with scar tissue, the total dose is fractionated, which means distributing the total dose over a period of time.

Typically, when treating neoplastic cells (basal and squamous-cell carcinomas), 8 to 12 fractions at a rate of 1 to 5 per week are used to deliver a total dose of 40-60 Gy, although larger PMENs may require up to 40 fractions over an 8-week period for a total dose of 80 Gy (Panizzon, R and Cooper, J. (Eds.) Radiation Treatment and Radiation Reactions in Dermatology, Springer Verlag, 2004, p. 75 – a copy is located in Appendix D).

When treating keloids, typically 1 to 4 fractions are employed, delivering a total dose in the range of 10 to 40 Gy. A summary of multiple clinical studies can be found in Section 20 of this 510(k) supported by literature located in Appendix D.

**Non-Clinical Performance Testing:**

Initial performance testing consisted of bench testing that demonstrated that the output of the Sensus Healthcare SRT-100 provided the same clinical capabilities as the predicate devices. The system successfully passed all tests required by *IEC 60601-1, Part 2-8, Edition*

***ORIGINAL***

*1.1, 1999 – Particular Requirements for the Safety of Therapeutic X-ray Equipment Operating in the Range 10 kV to 1 MV* and also tests developed internally for system characterization.

Additional performance testing was executed to validate the operational characteristics associated with the four additional applicators, (7.3 cm, 10.0 cm, 12.7, cm and 18x8 cm) needed for the treatment of keloids. The additional testing to support the addition of two applicators is discussed in Section 18 – Performance Testing – Bench.

**Non-clinical Safety Tests:**

The Sensus Healthcare SRT-100 has been designed and constructed to meet the following electrical and mechanical safety standards:

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (2<sup>nd</sup> edition)
- UL 60601-1: Medical Electrical Equipment, Part 1: General Requirements for Safety
- CAN/CSA-C22.2 NO. 601.1-M90 (R2005): Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2: medical equipment – Part 1: General requirements for safety. Collateral standard: electromagnetic compatibility – requirements and tests
- IEC 60601-1-4: Medical electrical equipment--Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems
- IEC 60601-2-8: Medical equipment – Part 2-8: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1MV
- IEC 60601-2-32: Medical electrical equipment Part 2: Particular requirements for the safety of associated equipment of X-ray equipment.

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Note 1: Sensus Healthcare acquired the Topex SRT-100 on June 28, 2010; and is the current owner of the intellectual properties, the manufacturer, and the distributor of the SRT-100.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Sensus Healthcare  
% Mr. Kal Fishman  
COO  
851 Broken Sound Pkwy NW #215  
BOCA RATON FL 33487

May 14, 2013

Re: K123985

Trade/Device Name: Sensus Healthcare Superficial Radiotherapy System SRT-100  
Regulation Number: 21 CFR 892.5900  
Regulation Name: X-ray radiation therapy system  
Regulatory Class: II  
Product Code: JAD  
Dated: April 1, 2013  
Received: April 4, 2013

Dear Mr. Fishman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

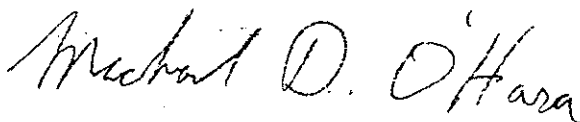
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Michael D. O'Hara". The signature is written in a cursive style with a large, stylized "M" and "O".

for

Janine M. Morris  
Director, Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K123985/S001

Device Name: Sensus Healthcare Superficial Radiotherapy System SRT-100

### Indications for Use:

The SRT-100 is a low energy X-ray system intended for superficial radiotherapy treatment of primary malignant epithelial neoplasms of the skin and keloids. Applications include basal cell carcinoma, squamous cell carcinoma, Metatypic carcinoma, cutaneous appendage carcinoma, Karposi's Sarcoma, and the treatment of keloids. Keloids are benign fibrous growths that arise from proliferation of dermal tissue typically arising from injuries to skin tissue.

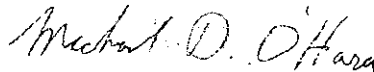
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign-Off)

Division of Radiological Health  
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K123985